

## **New data from the PRESTA trial demonstrate the benefit of Enbrel® in patients with psoriasis and psoriatic arthritis**

*Data presented at the 18th EADV Congress add to the comprehensive long-term data set as Enbrel reaches five-year anniversary in treating patients with plaque psoriasis in Europe*

**Wyeth Europa, Maidenhead, UK, 8 October 2009:** Data signalling that Enbrel® (etanercept) can improve the quality of life for people with psoriasis and psoriatic arthritis were presented at the 18th Congress of the European Academy of Dermatology and Venereology (EADV), as Enbrel® (etanercept) reached its five-year anniversary since its approval in Europe as a treatment for psoriasis.

People with psoriasis – a distressing skin condition characterised by red scaly patches – can often feel stigmatised as a result of their condition. They may feel anxious or depressed and some people with psoriasis experience a very low quality of life similar to, or even worse than, those individuals with other chronic medical diseases.

Recent results from the PRESTA study, one of the most extensive trials to evaluate patients with psoriatic arthritis, were presented at the EADV congress. These data focused on aspects of quality of life and improvement in potentially debilitating features such as dactylitis (inflammation of fingers and toes) and enthesitis (inflammation where bone meets ligament).

Data from the PRESTA study show that before starting Enbrel therapy, patients with both psoriasis and psoriatic arthritis had poor quality of life. A total of 95 per cent reported pain or discomfort, 71 per cent reported problems with mobility and 68 per cent reported problems conducting usual activities. Patients then took either 50mg Enbrel once (QW) or twice weekly (BiW) for 12 weeks, after which all patients took 50mg Enbrel once weekly for an additional 12 weeks. Improvement in quality of life for both groups was seen after the first three weeks on Enbrel, with a 36 per cent improvement achieved after 24 weeks of treatment. At that point, the proportion of patients reporting no pain or discomfort had increased by 35 per cent, patients reporting no problem with mobility had increased by 41 per cent and those reporting no problem conducting usual activities had increased by 37 per cent.

Between six and 42 per cent of people with psoriasis also suffer from psoriatic arthritis, a debilitating condition that can cause pain, swelling and stiffness in the hands and feet, larger joints such as the hips and knees, or the spine.

“Severe psoriasis can be ‘unsightly’ and the painful arthritic symptoms of psoriatic arthritis are physically disabling, often stopping us from carrying out day-to-day activities. However, it is important to remember that psoriasis is more than a skin and joint disease, which also affects patients psychologically as well as physically,” said Birgitte Snedker-Sørensen, psoriatic arthritis patient and Danmarks Psoriasis Forening representative. “The impact of these conditions can often make us feel embarrassed, depressed or anxious and withdraw from social interactions.

The PRESTA study also demonstrated that those patients receiving Enbrel showed a significant decrease in enthesitis and dactylitis at both 12 and 24 weeks:

- Of the patients presenting with enthesitis\*, 66 per cent in the Enbrel BiW/QW and 65 per cent in the Enbrel QW/QW groups had no enthesitis at 12 weeks, and
- 75 per cent and 76 per cent respectively achieved this response at week 24
- The mean total Dermatology Life Quality Index (DLQI) score in patients with enthesitis was more than halved at weeks 12 and 24 in both the Enbrel BiW/QW and QW/QW groups, reflecting a change in mean DLQI score from a very large effect on patient's life to a small effect on patient's life (13.4/12.6 at week 0 in the Enbrel BiW/QW groups to 4.6/5.5 at 12 weeks and 4.0/3.6 at 24 weeks respectively)
- Of the patients presenting with dactylitis, at week 12, the dactylitis mean per cent improvement from baseline was 74.3 per cent in the Enbrel BiW/QW and 68.8 per cent in the Enbrel QW/QW, and
- At week 24, the dactylitis mean per cent improvement from baseline was 82.2 per cent in the Enbrel BiW/QW and 76.6 per cent in the Enbrel QW/QW

\* 41 per cent of patients in the Enbrel BiW/QW group and 35 per cent in the Enbrel QW/QW had enthesitis at baseline.

In 2004, Enbrel was the first biologic treatment to be approved in Europe for the treatment of adults with moderate to severe plaque psoriasis where treatment with systemic agents is unsuitable, and has since been approved for the treatment of the same condition in children from the age of eight. Five years of 'real-life' experience demonstrating its effectiveness as a psoriasis treatment over the long-term was further confirmed with the recent approval in Europe of a continuous dosing indication.

"Over the five years that Enbrel has been available in Europe as a treatment for psoriasis, it has consistently proven to be a safe and effective treatment for psoriatic patients. Now, psoriatic patients stand to benefit from a greater choice of treatment: these data presented at EADV and the recent approval of the continuous dosing regimen for Enbrel, give patients and doctors the opportunity to tailor treatment in response to the severity of the patient's psoriasis and their ongoing response to treatment," said Professor Dr Wolfram Sterry, Humboldt University, Berlin, Germany.

Enbrel has been studied in over 3,000 adult and paediatric plaque psoriasis patients with clinical data now extending over 4 years.

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To access further media information relating to this press release, additional information on Enbrel and future media announcements, please register on the media centre at [www.wyeth.eu](http://www.wyeth.eu). If you subscribe to receive our emails you will get updates as soon as new content is added to the site. Please note you will be able to unsubscribe at any time and we will not pass your details on to any third party.

**NOTES TO EDITORS**

**ABOUT ENBREL**

Enbrel is a fully human soluble tumour necrosis factor (TNF) receptor. Enbrel was first approved in the EU in 2000 for moderate to severe rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, and has since been used in 505,000 patients worldwide across indications.

**Enbrel in the EU is approved for the following indications:**

**Rheumatoid arthritis**

Enbrel in combination with methotrexate is indicated for the treatment of moderate to severe active rheumatoid arthritis in adults when the response to disease-modifying antirheumatic drugs, including methotrexate (unless contraindicated), has been inadequate.

Enbrel can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.

Enbrel is also indicated in the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate.

Enbrel, alone or in combination with methotrexate, has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function.

**Polyarticular juvenile idiopathic arthritis**

Treatment of active polyarticular juvenile idiopathic arthritis in children and adolescents from the age of 4 years who have had an inadequate response to, or who have proved intolerant of, methotrexate. Enbrel has not been studied in children aged less than 4 years.

**Psoriatic arthritis**

Treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying antirheumatic drug therapy has been inadequate. Enbrel has been shown to improve

physical function in patients with psoriatic arthritis, and to reduce the rate of progression of peripheral joint damage as measured by X-ray in patients with polyarticular symmetrical subtypes of the disease.

**Ankylosing spondylitis**

Treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.

**Plaque psoriasis**

Treatment of adults with moderate to severe plaque psoriasis who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including ciclosporin, methotrexate or PUVA.

**Paediatric plaque psoriasis**

Treatment of chronic severe plaque psoriasis in children and adolescents from the age of 8 years who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.

**ABOUT WYETH:**

Wyeth is one of the world's largest research-based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of prescription drugs and over-the-counter medications. It is also a global leader in vaccines, biotechnology and animal health care.